REMARKS

Claims 1-23 are pending in this application.

In the outstanding Official Action, the Examiner has required restriction of claims 1-23 to a single invention under 35 U.S.C. §§ 121 and 372. Specifically, the Examiner asserts that the application contains more than one invention that are not so linked as to form a single general inventive concept under PCT Rule 13.1 Claims 1-23 were subjected to a restriction requirement as follows:

Group I - Claims 1-6, drawn to a composition comprising an adenoviral vector comprising an adenoviral capsid and a nucleic acid molecule comprising a retrogen cassette sequence;

Group II - Claims 7-23, drawn to a method of treating hepatocellular carcinoma; and

Group III- Claims 7-23 drawn to a method of treating HBV infection.

Applicants hereby provisionally elect claims 1-6 of Group I, with traverse. Applicants reserve the right to file a divisional application directed to the non-elected subject matter.

TRAVERSAL

Applicants respectfully traverse this restriction requirement because each of the "Groups" of claims that the Examiner alleges are "unrelated" share a ***special technical feature*** under PCT Rule 13.2. Accordingly, all of the presently pending claims possess unity of invention and restriction, therefore, is improper.

PCT Rule 13.2 states the following, in relevant part:

> [T]he requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical

features. The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In the present application, the special technical feature that is shared between Groups I-III is a composition comprising an adenoviral vector, wherein said adenoviral vector comprises: a) an adenoviral capsid, wherein said adenoviral capsid comprises subgroup B adenoviral capsid fibers selected from the group consisting of Adl1, Adl4, Adl6, Ad21, Ad34, Ad35, and Ad50; and b) a nucleic acid molecule, wherein said nucleic acid molecule comprises a retrogen cassette sequence encoding a retrogen protein, wherein said retrogen protein comprises: i) an antigen protein, ii) a leader sequence linked to the N-terminal of said antigen protein, and iii) a cell-binding domain linked to the C-terminal of said antigen protein. Therefore, Applicants respectfully submit that the claims of Group I-III possess "unity of invention" because they share a special technical feature as required by PCT Rule 13.2.

The Examiner asserts that Groups I-III do not share a special technical feature because the claimed method and composition were known at the time of filing as evidenced by You et al. (2000, Journal of Immunology, 165:4581-4592) and Bout et al. (US Patent No. 6,913,922). Applicants respectfully submit that the presently claimed composition is novel and non-obvious over each of You et al. and Bout et al. Accordingly, Applicants submit that Groups I-III share a special technical feature.

As asserted by the Examiner, You et al. teach that a retroviral vector comprising a nucleic acid sequence encoding a fusion protein comprising VH leader sequence, HBeAg, and a Fc domain was administered to dentritic cells. However, You et al. do not teach or

suggest the adenoviral vector used in the presently claimed composition. Therefore, Applicants submit that the presently claimed composition is novel and non-obvious over You et al.

Bout et al. teach a recombinant replication defective adenoviral vector comprising a gene of interest operatively linked to a promoter and at least one adenovirus capsid protein from adenovirus serotype Ad11 or Ad35. *See* Bout et al. at claim 1. In contrast to the presently claimed subject matter, Bout et al. do not teach or suggest that the gene of interest can be a retrogen cassette sequence encoding a retrogen protein comprising i) an antigen protein, ii) a leader sequence linked to the N-terminal of said antigen protein, and iii) a cell-binding domain linked to the C-terminal of said antigen protein. Further, as described in the present specification at page 15, lines 12-18, because the antigen-presenting pathway to MHC-class I is distinctively different from that to MHC-II, it is difficult for an antigen to be presented to both MHC-I and II by DCs. However, the retrogen cassette technology allows presentation of antigens to both MHC-I and MHC-II as well as potently activating Th, CTL and B-cells. Therefore, Applicants submit that the presently claimed composition is novel and non-obvious over Bout et al.

Furthermore, neither You et al. nor Bout et al. teach or suggest a combination of the adenoviral capsid with the nucleic acid molecule comprising a retrogen cassette sequence. Accordingly, Applicants respectfully submit that the presently claimed composition is novel and non-obvious You et al. in view of Bout et al.

Additionally, claims 7-23 are directed to a method using the presently claimed composition. Therefore, both Groups II and III have the same special technical feature as Group I. Accordingly, Applicants respectfully submit that the subject matter of Groups I, II and III relate to a single general inventive concept within the meaning of PCT Rules 13.1 and 13.2. Therefore, Applicants submit that restriction of the claims of Groups I-III is improper.

Further, MPEP § 803 specifies that restriction/election between two groups of claims is only proper when (1) one group of claims is independent ***or*** distinct from another group of claims and (2) a "serious burden" exists on the examiner in examining both groups of claims.

The Examiner can show a "serious burden" by establishing one of: the inventions are classified separately; the inventions have been classified together, but it can be shown that each subject has formed a separate subject for inventive effort (can cite patents or show a separate field of search); or the inventions require a separate field of search, that is, it is necessary to search for one subject in a place where no pertinent art for the other subject exists (MPEP § 808.02 (c)).

In the present application, the restriction requirement is traversed because it omits "an appropriate explanation" as to the existence of a "serious burden" if a restriction were not required between Groups I-III. *See* MPEP § 803. A complete and thorough search for the invention set forth in all of the alleged Groups would require searching the art areas appropriate to the other Groups. Since a search of each of the inventions of Groups I-III would be coextensive, it would not be a *serious* burden upon the Examiner to examine all of the claims in this application.

Furthermore, applicants have paid a filing fee for an examination of all the claims in this application. If the Examiner refuses to examine the claims paid for when filing this application and persists in requiring applicants to file divisional applications for each of the groups of claims, the Examiner would essentially be forcing applicants to pay duplicative fees for the non-elected or withdrawn claims, inasmuch as the original filing fees for the claims (which would be later prosecuted in divisional applications) are not refundable.

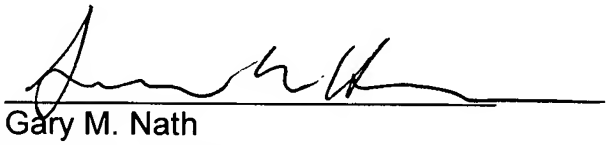
CONCLUSION

Having made the required election, examination on the merits is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP



Gary M. Nath
Reg. No. 26,965
Susanne M. Hopkins
Reg. No. 33,247
Ari G. Zytcer
Reg. No. 57,474
Customer No. 20529

January 30, 2008
THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
Tel: (703) 548-6284